IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-_____
	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vanda Pharmaceuticals Inc. ("Vanda") for its Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva") alleges as follows:

I. THE PARTIES

1. Plaintiff Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Ave. NW, Suite 300E, Washington, DC 20037. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including HETLIOZ® (tasimelteon oral capsules), for the treatment of Non-24-Hour Sleep-Wake Disorder ("Non-24").

2. On information and belief, Defendant Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

II. NATURE OF THE ACTION

3. This is an action arising under the patent laws of the United States (Title 35, U.S. Code, §§ 100, *et seq.*) based upon Teva's infringement of one or more claims of Vanda's U.S. Patent Nos. RE46,604 ("the RE604 patent"); 9,060,995 ("the '995 patent"); 9,539,234 ("the '234 patent"); 9,549,913 ("the '913 patent"); 9,730,910 ("the '910 patent"); and

9,855,241 ("the '241 patent") (collectively "the Asserted Patents"), which, in relevant part, generally relate to the use of tasimelteon in the treatment of Non-24.

4. Vanda is the holder of approved New Drug Application No. 205,677 for Hetlioz® (tasimelteon) capsules, 20 mg, which was approved by the Food and Drug Administration ("FDA") on January 31, 2014, for the treatment of Non-24 ("HETLIOZ® NDA").

5. Tasimelteon is the active ingredient in HETLIOZ®.

6. On information and belief, Teva filed Abbreviated New Drug Application No. 211601 (the "ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"), to obtain approval to commercially manufacture and sell generic tasimelteon capsules in its 20 mg strength for the treatment of Non-24 ("Teva's ANDA Product").

7. On information and belief, Teva made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the Asserted Patents are invalid, unenforceable, and/or that certain claims will not be infringed by Teva's ANDA Product.

8. Vanda received written notice of Teva's ANDA and Paragraph IV Certification on March 23, 2018 ("Notice Letter"), along with an enclosed statement of Teva's alleged factual and legal bases for stating that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by Teva's ANDA Product ("Detailed Statement").

9. Teva's Detailed Statement does not provide any separate factual bases for stating that the Asserted Patents will not be infringed by Teva's ANDA Product apart from arguing that the Asserted Patents are invalid.

10. Teva's Detailed Statement does not provide any factual bases for stating that the Asserted Patents are unenforceable.

11. This action is being commenced within 45 days of receipt of Teva's Notice Letter.

12. Teva has infringed one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Teva ANDA with a Paragraph IV Certification and seeking FDA approval of the Teva ANDA prior to the expiration of the Asserted Patents or any extensions thereof.

13. Teva has infringed one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of the Teva ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic tasimelteon for the treatment of Non-24 prior to the expiration of the Asserted Patents or any extensions thereof. Teva will infringe one or more claims of each of the Asserted Patents under 35 U.S.C. § 271(a), (b), or (c) should it engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 prior to the expiration of the Asserted Patents or any extensions thereof.

III. JURISDICTION

14. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over Vanda's patent infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Teva because Teva is incorporated in the State of Delaware.

16. On information and belief, Teva's registered agent for service of process is Corporate Creations Network, Inc., with an address at 3411 Silverside Road #104, Tatnall Building, Wilmington, Delaware 19810.

17. On information and belief, Teva is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of Delaware and throughout the United States.

18. Teva has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Vanda, which manufactures HETLIOZ® for sale and use throughout the United States, including in this judicial District. On information and belief, and as indicated by the Notice Letter, Teva prepared and filed ANDA No. 211601 with the intention of seeking to market generic tasimelteon nationwide, including within this judicial District.

19. On information and belief, Teva plans to market and sell generic tasimelteon in the State of Delaware, list generic tasimelteon on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursement for sales of the ANDA products in the State of Delaware, either directly or through one or more of Teva's wholly owned subsidiaries, agents, and/or alter egos.

20. On information and belief, Teva knows and intends that its proposed generic tasimelteon product will be distributed and sold in Delaware and will thereby displace sales of HETLIOZ®, causing injury to Vanda. Teva intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic tasimelteon product.

IV. VENUE

21. Venue is proper in this judicial District under 28 U.S.C. § 1400(b) because Teva is incorporated in the State of Delaware.

V. THE PATENTS-IN-SUIT

(U.S. PATENT NOS. RE46,604; 9,060,995; 9,539,234; 9,549,913; 9,730,910; 9,855,241)

22. The allegations above are incorporated herein by reference.

23. The Asserted Patents cover the use of tasimelteon to treat patients with Non-24.

24. As explained in the Asserted Patents, "Non-24 occurs when individuals, primarily blind with no light perception, are unable to synchronize their endogenous circadian pacemaker to the 24-hour light/dark cycle. Without light as a synchronizer, and because the period of the internal clock is typically a little longer than 24 hours, individuals with Non-24 experience their circadian drive to initiate sleep drifting later and later each day. Individuals with Non-24 have abnormal night sleep patterns, accompanied by difficulty staying awake during the day." As also explained in the Asserted Patents, "[t]he ultimate treatment goal for individuals with Non-24 is to entrain or synchronize their circadian rhythms into an appropriate phase relationship with the 24-hour day so that they will have increased sleepiness during the night and increased wakefulness during the daytime."

25. The Asserted Patents explain that "Tasimelteon is a circadian regulator which binds specifically to two high affinity melatonin receptors, Mel1a (MT1R) and Mel1b (MT2R). These receptors are found in high density in the suprachiasmatic nucleus of the brain (SCN), which is responsible for synchronizing our sleep/wake cycle."

U.S. Patent No. RE46,604

26. Vanda is the owner of all rights, title, and interest in the RE604 patent, entitled "Treatment of Circadian Rhythm Disorders." The USPTO duly and legally issued the RE604 patent (a reissue patent) on November 14, 2017, to Marlene M. Dressman, John J. Feeney, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned

to Vanda. A true and correct copy of the RE604 patent is attached to this Complaint as Exhibit A.

27. The RE604 patent generally claims methods of treating Non-24 by orally administering 20 mg of tasimelteon once daily before bedtime. As an example, claim 1 of the RE604 patent claims: "A method of entraining a patient suffering from Non-24 to a 24 hour sleep-wake cycle in which the patient awakens at or near a target wake time following a daily sleep period of approximately 7 to 9 hours, and maintaining said 24 hour sleep-wake cycle said method comprising: treating the patient by orally administering to the patient 20 mg of tasimelteon once daily before a target bedtime."

28. The RE604 patent also claims methods of treating Non-24 by avoiding the use of tasimelteon in combination with a CYP1A2 inhibitor, such as fluvoxamine. As an example, claim 6 of the RE604 patent claims "The method of claim 1 further comprising: (i) first determining if the patient is also being treated with a CYP1A2 inhibitor, and (ii) if the patient is being treated with a CYP1A2 inhibitor, reducing the dose of the CYP1A2 inhibitor." And claim 7 of the RE604 patent claims: "The method of claim 6 wherein the CYP1A2 inhibitor is ciprofloxacin, fluvoxamine, or verapamil."

U.S. Patent No. 9,060,995

29. Vanda is the owner of all rights, title, and interest in the '995 patent, entitled "Treatment of Circadian Rhythm Disorders." The USPTO duly and legally issued the '995 patent on June 23, 2015, to Marlene M. Dressman, John J. Feeney, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '995 patent is attached to this Complaint as Exhibit B.

30. The '995 patent generally claims a method of treating Non-24 by avoiding the use of tasimelteon in combination with fluvoxamine. The sole claim, claim 1, claims "A

method of entraining a light perception impaired patient suffering from Non-24-Hour Sleep-Wake Disorder to a 24-hour sleep-wake cycle in which the patient awakens at or near a target wake time following a daily sleep period of approximately 7 to 9 hours, wherein the patient is being treated with fluvoxamine, the method comprising: (A) discontinuing the fluvoxamine treatment and then (B) orally treating the patient with 20 mg of tasimelteon once daily before a target bedtime, thereby avoiding the use of tasimelteon in combination with fluvoxamine."

U.S. Patent No. 9,539,234

31. Vanda is the owner of all rights, title and interest in the '234 patent, entitled "Treatment of Circadian Rhythm Disorders." The USPTO duly and legally issued the '234 patent on January 10, 2017, to Marlene M. Dressman, John J. Feeney, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '234 patent is attached to this Complaint as Exhibit C.

32. The '234 patent generally claims methods of treating Non-24 by avoiding the use of tasimelteon in combination with a strong CYP1A2 inhibitor. For example, claim 3, which depends from claim 1, claims "The method of claim 1, that comprises treating the patient for Non-24-Hour Sleep-Wake Disorder wherein the patient is light perception impaired (LPI)."

U.S. Patent No. 9,549,913

33. Vanda is the owner of all rights, title, and interest in the '913 patent, entitled "Treatment of Circadian Rhythm Disorders." The USPTO duly and legally issued the '913 patent on January 24, 2017, to Marlene M. Dressman, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '913 patent is attached to this Complaint as Exhibit D.

34. The '913 patent generally claims methods of entraining a patient's cortisol circadian rhythm to a 24-hour circadian rhythm and maintaining that 24-hour circadian rhythm

by orally administering to the patient tasimelteon once daily before a target bedtime. For example, claim 1 claims "A method of entraining a patient's cortisol circadian rhythm to a 24-hour circadian rhythm and maintaining said 24-hour circadian rhythm, the method comprising: treating the patient by orally administering to the patient tasimelteon once daily before a target bedtime." For example, claim 4 claims "The method of claim 1, wherein the patient suffers from Non-24-Hour Sleep-Wake Disorder."

U.S. Patent No. 9,730,910

35. Vanda is the owner of all rights, title, and interest in the '910 patent, entitled "Treatment of Circadian Rhythm Disorders." The USPTO duly and legally issued the '910 patent on August 15, 2017, to Marlene M. Dressman, John J. Feeney, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '910 patent is attached to this Complaint as Exhibit E.

36. The '910 patent generally claims methods of treating Non-24 by avoiding the use of tasimelteon in combination with rifampin. For example, claim 2, which depends from claim 1, claims "The method of claim 1 that comprises treating the patient for Non-24-Hour Sleep-Wake Disorder." Claim 1 claims "A method of treating a patient for a circadian rhythm disorder wherein the patient is being treated with rifampicin, the method comprising: (A) discontinuing the rifampicin treatment and then (B) treating the patient with tasimelteon, thereby avoiding the use of tasimelteon in combination with rifampicin and also thereby avoiding reduced exposure to tasimelteon caused by induction of CYP3A4 by rifampicin."

37. Rifampicin is also known as rifampin.

U.S. Patent No. 9,855,241

38. Vanda is the owner of all rights, title, and interest in the '241 patent, entitled "Treatment of Circadian Rhythm Disorders." The USPTO duly and legally issued the

'241 patent on January 2, 2018, to Marlene M. Dressman, Louise W. Licamele, and Mihael H. Polymeropoulos as inventors, which was assigned to Vanda. A true and correct copy of the '241 patent is attached to this Complaint as Exhibit F.

39. The '241 patent generally claims methods of synchronizing a patient's abnormal cortisol circadian rhythm and abnormal melatonin circadian rhythm with a natural day/night cycle by treating the patient by orally administering to the patient an effective amount of tasimelteon once daily before a target bedtime. For example, claim 4, which depends from claim 1, claims "The method of claim 1, wherein the patient suffers from Non-24-Hour Sleep-Wake Disorder." Claim 1 claims "A method of synchronizing a patient's abnormal cortisol circadian rhythm and abnormal melatonin circadian rhythm with a natural day/night cycle, the method comprising: treating the patient by orally administering to the patient an effective amount of tasimelteon once daily before a target bedtime."

VI. COUNT I

(INFRINGEMENT OF THE RE604 PATENT)

40. The allegations above are incorporated herein by reference.

41. Teva filed the Teva ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the RE604 patent and any extensions thereof.

42. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the RE604 patent. The Notice Letter represents that Teva's ANDA was submitted with a Paragraph IV Certification that the RE604 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

43. Teva thus has actual knowledge of the RE604 patent.

44. Teva's Detailed Statement does not provide any separate legal or factual bases for stating that the RE604 patent will not be infringed by Teva's ANDA Product apart from arguing that the RE604 patent is invalid.

45. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

46. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

47. The HETLIOZ® Label further instructs physicians to "[a]void use of HETLIOZ in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions."

48. On information and belief, the Teva ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

49. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the RE604 patent, and Vanda has the right to enforce the RE604 patent and sue for infringement thereof.

50. The RE604 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for HETLIOZ® in its 20 mg strength.

51. On information and belief, the Teva ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs,

recommends, encourages, and/or suggests physicians to infringe at least claims 1, 6, and 7 of the RE604 patent.

52. On information and belief, Teva's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1, 6, and 7 of the RE604 patent.

53. Teva has infringed the RE604 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength for the treatment of Non-24, which is covered by one or more claims of the RE604 patent, prior to the expiration of the RE604 patent.

54. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the RE604 patent, including at least claims 1, 6, and 7 under 35 U.S.C. § 271(a), (b), and/or (c).

55. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

56. Vanda seeks entry of an order declaring that Teva has infringed the RE604 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

57. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date that is not earlier than the expiration of the RE604 patent or any later expiration of exclusivity for the RE604 patent to which Vanda becomes entitled.

58. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the RE604 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

59. On information and belief, Teva's statement of the factual and legal bases for its opinion regarding the invalidity and noninfringement of the RE604 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

60. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

VII. COUNT II

(INFRINGEMENT OF THE '995 PATENT)

61. The allegations above are incorporated herein by reference.

62. Teva filed the Teva ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '995 patent and any extensions thereof.

63. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '995 patent. The Notice Letter represents that the Teva ANDA was submitted with a Paragraph IV Certification that the '995 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

64. Teva thus has actual knowledge of the '995 patent.

65. Teva's Detailed Statement does not provide any separate legal or factual bases for stating that the '995 patent will not be infringed by Teva's ANDA Product apart from arguing that the '995 patent is invalid.

66. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

67. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

68. The HETLIOZ® Label further instructs physicians to "[a]void use of HETLIOZ in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions."

69. On information and belief, the Teva ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

70. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '995 patent, and Vanda has the right to enforce the '995 patent and sue for infringement thereof.

71. The '995 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

72. On information and belief, the Teva ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe claim 1 of the '995 patent.

73. On information and belief, Teva's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe claim 1 of the '995 patent.

74. Teva has infringed the '995 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic tasimelteon in its 20 mg strength for the treatment of Non-24, which is covered by claim 1 of the '995 patent, prior to the expiration of the '995 patent.

75. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of claim 1 of the '995 patent under 35 U.S.C. § 271(a), (b), and/or (c).

76. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

77. Vanda seeks entry of an order declaring that Teva has infringed the '995 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

78. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date that is not earlier than the expiration of the '995 patent or any later expiration of exclusivity for the '995 patent to which Vanda becomes entitled.

79. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of claim 1 of the '995 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

80. On information and belief, Teva's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '995 patent is devoid of an

objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

81. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

VIII. COUNT III

(INFRINGEMENT OF THE '234 PATENT)

82. The allegations above are incorporated herein by reference.

83. Teva filed the Teva ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '234 patent, and any extensions thereof.

84. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '234 patent. The Notice Letter represents that the Teva ANDA was submitted with a Paragraph IV Certification that the '234 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

85. Teva thus has actual knowledge of the '234 patent.

86. Teva's Detailed Statement does not provide any separate legal or factual bases for stating that the '234 patent will not be infringed by Teva's ANDA Product apart from arguing that the '234 patent is invalid.

87. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

88. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

89. The HETLIOZ® Label further instructs physicians to "[a]void use of HETLIOZ in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions," and to "[a]void use of HETLIOZ in combination with strong CYP1A2 inhibitors because of increased exposure."

90. On information and belief, the Teva ANDA seeks approval for a 20mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

91. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '234 patent, and Vanda has the right to enforce the '234 patent and sue for infringement thereof.

92. The '234 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

93. On information and belief, the Teva ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claim 3 of the '234 patent.

94. On information and belief, Teva's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 3 of the '234 patent.

95. Teva has infringed the '234 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic

tasimelteon in its 20 mg strength, for the treatment of Non-24, which is covered by one or more claims of the '234 patent, prior to the expiration of the '234 patent.

96. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '234 patent, including at least claim 3, under 35 U.S.C. § 271(a), (b), and/or (c).

97. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

98. Vanda seeks entry of an order declaring that Teva has infringed the '234 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

99. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date that is not earlier than the expiration of the '234 patent or any later expiration of exclusivity for the '234 patent to which Vanda becomes entitled.

100. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '234 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

101. On information and belief, Teva's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '234 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

102. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

IX. COUNT IV

(INFRINGEMENT OF THE '913 PATENT)

103. The allegations above are incorporated herein by reference.

104. Teva filed the Teva ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '913 patent and any extensions thereof.

105. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '913 patent. The Notice Letter represents that the Teva ANDA was submitted with a Paragraph IV Certification that the '913 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

106. Teva thus has actual knowledge of the '913 patent.

107. Teva's Detailed Statement does not provide any separate legal or factual bases for stating that the '913 patent will not be infringed by Teva's ANDA Product apart from arguing that the '913 patent is invalid.

108. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

109. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

110. On information and belief, the Teva ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

111. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '913 patent, and Vanda has the right to enforce the '913 patent and sue for infringement thereof.

112. The '913 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

113. On information and belief, the Teva ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claims 1 and 4 of the '913 patent.

114. On information and belief, Teva's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claims 1 and 4 of the '913 patent.

115. Teva has infringed the '913 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic tasimelteon, in its 20 mg strength, for the treatment of Non-24, which is covered by one or more claims of the '913 patent, to the expiration of the '913 patent.

116. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '913 patent, including at least claims 1 and 4, under 35 U.S.C. § 271(a), (b), and/or (c).

117. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

118. Vanda seeks entry of an order declaring that Teva has infringed the '913 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

119. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date that is not earlier than the expiration of the '913 patent or any later expiration of exclusivity for the '913 patent to which Vanda becomes entitled.

120. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the '913 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

121. On information and belief, Teva's statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the '913 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys' fees pursuant to 35 U.S.C. § 285.

122. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

X. COUNT V

(INFRINGEMENT OF THE '910 PATENT)

123. The allegations above are incorporated herein by reference.

124. Teva filed the Teva ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '910 patent and any extensions thereof.

125. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '910 patent. The Notice Letter represents that the Teva ANDA was submitted with a Paragraph IV Certification that the '910 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

126. Teva thus has actual knowledge of the '910 patent.

127. Teva's Detailed Statement does not provide any separate legal or factual bases for stating that the '910 patent will not be infringed by Teva's ANDA Product apart from arguing that the '910 patent is invalid.

128. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

129. The HETLIOZ® Label further instructs physicians that "The recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

130. The HETLIOZ® Label further instructs physicians to "Avoid use of HETLIOZ in combination with rifampin or other CYP3A4 inducers because of a potentially large decrease in tasimelteon exposure with reduced efficacy," and to "Avoid use of HETLIOZ in combination with rifampin or other CYP3A4 inducers, because of decreased exposure."

131. On information and belief, the Teva ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

132. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '910 patent, and Vanda has the right to enforce the '910 patent and sue for infringement thereof.

133. The '910 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

134. On information and belief, the Teva ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claim 2 of the '910 patent.

135. On information and belief, Teva's ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 2 of the '910 patent.

136. Teva has infringed the '910 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic tasimelteon, in its 20 mg strength, for the treatment of Non-24, which is covered by one or more claims of the '910 patent, prior to the expiration of the '910 patent.

137. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the '910 patent, including at least claim 2, under 35 U.S.C. § 271(a), (b), and/or (c).

138. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

139. Vanda seeks entry of an order declaring that Teva has infringed the ’910 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

140. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date that is not earlier than the expiration of the ’910 patent or any later expiration of exclusivity for the ’910 patent to which Vanda becomes entitled.

141. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the ’910 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

142. On information and belief, Teva’s statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the ’910 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys’ fees pursuant to 35 U.S.C. § 285.

143. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

XI. COUNT VI

(INFRINGEMENT OF THE ’241 PATENT)

144. The allegations above are incorporated herein by reference.

145. Teva filed the Teva ANDA under § 505(j) of the FFDCA to obtain approval to commercially manufacture, use, offer to sell, and sell generic tasimelteon for the treatment of Non-24 before the expiration of the '241 patent and any extensions thereof.

146. Teva's Notice Letter states that Teva filed the ANDA seeking approval to manufacture, use, offer to sell, and sell generic tasimelteon in its 20 mg strength for the treatment of Non-24 before the expiration of the '241 patent. The Notice Letter represents that the Teva ANDA was submitted with a Paragraph IV Certification that the '241 patent purportedly is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

147. Teva thus has actual knowledge of the '241 patent.

148. Teva's Detailed Statement does not provide any separate legal or factual bases for stating that the '241 patent will not be infringed by Teva's ANDA Product apart from arguing that the '241 patent is invalid.

149. The FDA-approved HETLIOZ® Label instructs physicians that "HETLIOZ is indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)."

150. The HETLIOZ® Label further instructs physicians that "[t]he recommended dosage of HETLIOZ is 20 mg per day taken before bedtime, at the same time every night."

151. On information and belief, the Teva ANDA seeks approval for a 20 mg tasimelteon oral capsule for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24).

152. Thus, the use of HETLIOZ® and any generic tasimelteon for the treatment of Non-24 is covered by the '241 patent, and Vanda has the right to enforce the '241 patent and sue for infringement thereof.

153. The ’241 patent is listed in the Orange Book for HETLIOZ® in its 20 mg strength.

154. On information and belief, the Teva ANDA essentially copies the HETLIOZ® Label as required by FDA, *see* 21 C.F.R. § 314.94(a)(iv), and therefore instructs, recommends, encourages, and/or suggests physicians to infringe at least claim 4 of the ’241 patent.

155. On information and belief, Teva’s ANDA Product is not a staple article of commerce and has no substantial uses that do not infringe at least claim 4 of the ’241 patent.

156. Teva has infringed the ’241 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its submission of the Teva ANDA to FDA seeking to obtain approval for generic tasimelteon, in its 20 mg strength, for the treatment of Non-24, which is covered by one or more claims of the ’241 patent, prior to the expiration of the ’241 patent.

157. The commercial manufacture, use, offer to sell, sale, distribution, or importation of products under the Teva ANDA would infringe directly or contribute to or induce the infringement of one or more claims of the ’241 patent, including at least claim 4, under 35 U.S.C. § 271(a), (b), and/or (c).

158. Vanda seeks entry of an order requiring that Teva amend its Paragraph IV Certification in the Teva ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

159. Vanda seeks entry of an order declaring that Teva has infringed the ’241 patent by virtue of submitting its ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

160. Vanda seeks entry of an order pursuant to 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any FDA approval of the Teva ANDA be a date

that is not earlier than the expiration of the ’241 patent, or any later expiration of exclusivity for the ’241 patent to which Vanda becomes entitled.

161. Vanda will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of one or more claims of the ’241 patent. Pursuant to 35 U.S.C. § 283, Vanda is entitled to a permanent injunction against further infringement. Vanda does not have an adequate remedy at law.

162. On information and belief, Teva’s statement of the factual and legal basis for its opinion regarding the invalidity and noninfringement of the ’241 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Vanda is entitled to attorneys’ fees pursuant to 35 U.S.C. § 285.

163. To the extent Teva commercializes its product, Vanda will also be entitled to damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that this Court enter judgment in its favor against Teva and grant the following relief:

A. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the RE604 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the RE604 patent;

B. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the ’995 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use,

offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the ’995 patent;

C. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the ’234 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the ’234 patent;

D. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the ’913 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the ’913 patent;

E. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the ’910 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the ’910 patent;

F. an adjudication that Teva has infringed directly, contributed to, or induced the infringement of one or more claims of the ’241 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to FDA the Teva ANDA to obtain approval for the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic tasimelteon for the treatment of Non-24 before the expiration of the ’241 patent;

G. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the RE604 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the RE604 patent;

H. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the ’995 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the ’995 patent;

I. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the ’234 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the ’234 patent;

J. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the ’913 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the ’913 patent;

K. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the ’910 patent under 35 U.S.C. § 271(a), (b), and/or (c) if it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the ’910 patent;

L. a declaration that Teva will infringe directly, contribute to, or induce the infringement of one or more claims of the ’241 patent under 35 U.S.C. § 271(a), (b), and/or (c) if

it markets, manufactures, uses, offers for sale, sells, distributes in, or imports into the United States generic tasimelteon for the treatment of Non-24 before the expiration of the '241 patent;

M. an order requiring that Teva amend its Paragraph IV Certification to a Paragraph III certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

N. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Teva ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the RE604 patent or any later period of exclusivity to which Vanda is or may become entitled;

O. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Teva ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '995 patent or any later period of exclusivity to which Vanda is or may become entitled;

P. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Teva ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '234 patent or any later period of exclusivity to which Vanda is or may become entitled;

Q. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Teva ANDA for generic tasimelteon be a date that is not earlier than the date of the expiration of the '913 patent or any later period of exclusivity to which Vanda is or may become entitled;

R. an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Teva ANDA for generic tasimelteon be a date that is not earlier

than the date of the expiration of the ’241 patent or any later period of exclusivity to which Vanda is or may become entitled;

S. a permanent injunction enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the RE604 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

T. a permanent injunction enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’995 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

U. a permanent injunction enjoining Teva, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’234 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

V. a permanent injunction enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’913 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

W. a permanent injunction enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’241 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

X. a permanent injunction enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’910 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA;

Y. an order enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the RE604 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA while the litigation is pending;

Z. an order enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’995 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA while the litigation is pending;

AA. an order enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’913 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA while the litigation is pending;

BB. an order enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’234 patent, contributing to, or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA while the litigation is pending;

CC. an order enjoining Teva, its officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or participation with any of them from infringing the ’241 patent, or contributing to or inducing anyone to do the same, including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of the product described in the Teva ANDA while the litigation is pending;

DD. an assessment of pre-judgment and post-judgment interest and costs against Teva, together with an award of such interest and costs, in accordance with 35 U.S.C. § 284;

EE. an award to Vanda of its attorneys’ fees incurred in connection with this lawsuit pursuant to 35 U.S.C. § 285; and

FF. such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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